UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

VB

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/367,629	10/18/99	GUPTA	A 9403-2

HM22/1205

SEIDEL GONDA LAVORGNA & MONACO
TWO PENN CENTER PLAZA
SUITE 1800
PHILADELPHIA PA 19102

EXAMINER	
CHAUDHRY, M	
ART UNIT	**PAPER NUMBER**
1623	8

DATE MAILED: 12/05/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/367,629	Applicant(s) GUPTA, AJAY	
	Examiner Mahreen Chaudhry	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-50 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-50 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. Claims 1, 2, 19, 22, 33, 36, 39, 40 and 41 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WO 2000059493 published by Khalifah et al. The Khalifah reference indicates that it claims priority to U.S. application 60/127906 filed April 6, 1999 which claims priority to U.S. Patent 5,985,857, issued to Hudson et al., which claims priority to September 1995. In WO 2000059493, Khalifah et al. disclose the addition of advanced glycation end-product inhibitors, including Vitamin B_1 and Vitamin B_6 derivatives, to dialysis solutions in order to treat disorders associated with dialysis (abstract). In U.S. Patent 5,985,857, Hudson et al. disclose that Vitamin B_6 itself, Vitamin B_6 derivatives and the physiologically active form of Vitamin B_1, thiamine pyrophosphate, inhibit advanced glycation end-products (Column 11, Lines 9-31). It is well-known in the art that advanced glycation end-products accumulate in the tissues of patients undergoing dialysis and that these advanced glycation end-products are associated with several adverse effects.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 3-12, 23-24, 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khalifah et al. Neither Khalifah et al. nor Hudson et al. specifically disclose the use of physiological or supraphysiological amounts of Vitamin B_1 or Vitamin B_6 to dialysis solution. However, Khalifah et al. do teach that the addition of AGE inhibitors, such as Vitamin B_1 and Vitamin B_6 derivatives, may be utilized to treat dialysis-related complications. It would have been obvious to one having ordinary skill in the art that the addition of either physiological or supraphysiological amounts of the AGE inhibitors, such as Vitamin B_1 and Vitamin B_6 derivatives, would have been necessary in order to appropriately treat vitamin deficiency in individuals undergoing dialysis.

5. Claims 16-18, 20, 31-34, 38, 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khalifah et al. in view of U.S. Patent 4,237,167 issued to Cavazza et al. Cavazza et al. disclose the addition of acyl-carnitine to a dialysis solution in order to supplement depleted carnitine in patients undergoing dialysis (Column 3, Lines 49-60). Cavazza et al. further teach the dialysis solution may contain a quantity of acyl-carnitine that is equimolar to plasma carnitine or a more concentrated solution (Column 3, Lines 65+). Cavazza et al.

specifically teach that the dialysis solution contains 50 to 100 umol/L of acyl-carnitine (Column 4, Lines 4-6). It would therefore have been obvious to one having ordinary skill in the art to have added Vitamin B_1 and/or Vitamin B_6 to a dialysis solution as taught by Khalifah et al. and to also have added carnitine to the dialysis solution as taught by Cavazza et al.

6. Claim 13-15, 29-30 and 37 rejected under 35 U.S.C. 103(a) as being unpatentable over Khalifah et al. in view of Pru et al. Pru et al. disclose that vitamin C can be added to the dialysate in order to treat the vitamin C deficiency occurring in patients on hemodialaysis (abstract). Pru et al. does not expressly disclose that vitamin C can be added to peritoneal dialysis solution; however, since patients undergoing peritoneal dialysis, like those undergoing hemodialysis, suffer from vitamin C deficiency, it would have been obvious to one having ordinary skill in the art to have added vitamin C to periotneal dialysis solutions. Neither Pru et al. nor Khalifah et al. specifically disclose that vitamin B_1, vitamin B_6 or vitamin C can be added to a dialysis solution together. However, it would have been obvious to one having ordinary skill in the art that to have added these vitamins to the dialysis solutions together since dialysis patients are known to suffer from deficiencies in vitamin B_1, vitamin B_6 and vitamin C and doing so would allow the treatment of several vitamin deficiencies at one time. Furthermore, it would have been obvious to have added vitamin C at a concentration appropriate to treat its deficiency.

7. Claim 5-6, 11-12, 21, 25, 35, 43 and 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khalifah et al. in view of both Cavazza et al. and Pru et al. Cavazza et al. teach that carnitine can be added to dialysis solution in order to treat carnitine deficiency. Pru et

al. teach that Vitamin C can similarly be added to a dialysis solution in order to treat vitamin C deficiency. Khalifah et al. teach that vitamin B_1 and vitamin B_6 derivatives can be added to dialysis solutions in order to treat complications resulting from dialysis. Cavazza et al., Pru et al. and Khalifah et al. teach the addition of vitamins and nutrients to dialysis solutions in order to treat known deficiencies of these vitamins and nutrients in dialysis patients. It would therefore have been obvious to one having ordinary skill in the art to have added either folic acid and vitamin B_{12}, either alone, in combination with each other or in combination with vitamin B_1, vitamin B_6 or vitamin C, since dialysis patients are known to suffer from deficiencies of these vitamins. Furthermore, it would have been obvious to one having ordinary skill in the art to have added other nutrients, such as iron or zinc, in appropriate forms, to such dialysis solution since these nutrients are also known to be decreased in patients undergoing dialysis and doing so would allow the treatment of several deficiencies at one time.

8. Claims 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,563,126 issued to Allen et al. in 1996. Allen et al. disclose vitamin preparations comprising vitamin B_{12}, vitamin B_6 and folic acid (Column 1, Lines 14-19).

Claims 44-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,635,199 issued to Trimbo et al. Trimbo et al. a solution for nutritional support consisting of vitamin B_{12}, vitamin B_6, folic acid, vitamin C, thiamine and carnitine (Column 6, Lines 20-30).

Neither Allen et al. or Trimbo et al. disclose the use of these composition in dialysis solutions; however, the intended use of a product is not patentable.

9. A CAPLUS abstract of WO 2000059493 is being provided in place of the entire document for the sake of convenience. This document can be provided upon request.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mahreen Chaudhry whose telephone number is (703) 605-1200. The examiner can normally be reached on Monday – Friday (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist, can be reached on (703) 308-1701 . The official fax phone number for the organization where this application is proceeding or assigned is (703) 308-4556 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

mc
November 16, 2000

PAUL J. KILLOS
PRIMARY EXAMINER
1623